

Drug Utilization Review Board

Meeting Minutes

Thursday, June 14, 2018
7:15 a.m. to 8:30 a.m.
Cannon Health Building
Room 125

Board Members Present:

Kumar Shah, MSc, PEng, Board Chair
Jennifer Brinton, MD
Eric Cannon, PharmD, FAMCP
Neal Catalano, PharmD
Aesha Drozdowski, PharmD

Steve Lore, MD
Kim Michelson, DDS
Katherine Smith, PharmD
Susan Siegfried, MD

Board Members Excused:

Ben Berrett, PharmD

Sharon Weinstein, M.D.

Dept. of Health/Div. of Health Care Financing Staff Present:

Jennifer Strohecker, PharmD, Director
Robyn Seely, PharmD
Bryan Larson, PharmD

Joe Busby, RPh
Merelynn Berrett, RN, PA

University of Utah Drug Regimen Review Center Staff Presenter:

Elena Martinez, PharmD

Other Individuals Present:

Elena Martinez Alonso, U of U
Joanita Lake, U of U
Valerie Gonzales, U of U
Dar Manning, Spark
Lillian Chen, Spark
Susan Kelly, Spark
Paul Bonham, Avexis

Jeff Mussack, Otsuka
John Zabukovez, Conduent
Charissa Anne, J&J
Scott Clegg, Lilly
Jason Bott, Lilly
Lori Howarth, Bayer

Meeting conducted by: Kumar Shah

- Welcome & Housekeeping:** Kumar Shah opened the meeting. Robyn Seely reminded everyone to sign the rosters and asked new staff members Jennifer Strohecker, Pharmacy Director, and Joe Busby, Peer-to-Peer Pharmacist, to introduce themselves.
- Review and Approval of April Minutes:** Eric Cannon made a motion to approve the April minutes (there was no meeting in May). Neal Catalano seconded the motion. All in favor; motion passed.
- Annual Declaration of Conflicts of Interest:** Board members sign a yearly statement of actual or potential conflicts of interest with Board activities. These statements will be signed next month.
- Pharmacy and Therapeutics Update:** The Committee reviewed proton pump inhibitors in May, and will review HMG-CoA reductase inhibitors ("statins") on June 21, 2018, and treatments

for hemophilia on July 19, 2018

5. **Nine-Month review:** Nine months ago, codeine use in children was presented. The Board requested a review of the topic in 12 to 18 months, rather than nine months.
6. **Infliximab Step-Through: Inflectra preferred:** Joe Busby mentioned that of the identically-acting biosimilar agents Inflectra, Renflexis, and Remicade. Renflexis is the least costly, and its use will be required first unless a prior authorization (PA) is acquired.

7. **Luxturna (voretigene nepavovec-rzyl):**

a. **Information:**

Elena Martinez presented a review of Luxturna, a gene therapy treatment of Biallelic RPE mutation-associated retinal dystrophy. She presented peer-reviewed research regarding its safety and efficacy, clinical trials, disease-state treatment guidelines and Utah Medicaid utilization data.

b. **Board Discussion:**

Jennifer Brinton mentioned the previous week's article in the Journal of the American Medical Association regarding value-based pricing, which used Luxturna as an example. Bryan Larson noted that several states and pharmaceutical companies are beginning to explore value-based pricing.

Aesha Drozdowski noted that the FDA approved Luxturna for patients 12 months and older, although studies only involved patients aged 3 years and older. Jennifer Brinton and Steve Lore noted the enormous eye maturation that occurs in those 24 month, and the vision salvage that could occur if treatment could start earlier. Earlier treatment would be/is very advantageous.

The 58 Utah Medicaid patients with related diagnosis codes, listed in the report, were discussed. Candidates for Luxturna would be a small subset of these patients, not all of these patients. Utah Medicaid has not received any requests for Luxturna.

c. **Public Comment:**

1. Lillian Chen, Spark

Studies only included patients 3 years and older because study end points included ability to navigate a maze; patients under 3 may not have the motor skills needed to complete the task.

There are 9 treatment centers in the United States approved to administer Luxturna; none in Utah. They are listed on the Spark patient services website.

Lillian Chen mentioned Dr. Bernstein's letter (below); in 23 years of practice he has seen two patients that would have been candidates for Luxturna had the drug been available earlier in the course of their disease.

2. Letter from Paul Bernstein, Moran Eye Center, U of U Prof of Ophthalmology, read aloud by Robyn Seely.

d. Board Discussion, Continued:

Bryan Larson and Robyn Seely gave a quick overview of out-of-state treatment: transportation, lodging, provider enrollment, etc.

Lillian Chen, upon invitation from the Board, noted that the condition has been known in the past by different names, depending on age of diagnosis, but genetic testing now accurately identifies it and thus it's appropriate treatment.

Lillian Chen, upon invitation from the Board, briefly described the training Spark provides to pharmacists involved in Luxturna's administration.

Jennifer Brinton suggested that prior authorization (PA) criteria include genetic testing to confirm the presence of Biallelic RPE65 mutations, and age greater-than-or-equal-to 12 months. Kim Michelson suggested that PA criteria include the presence of viable retinal cells. Aesha Drozdowski suggested a single injection in each eye, at least six days apart. Steve Lore noted that simplicity is best. Robyn Seely suggested once per lifetime; Bryan Larson suggested once per eye per lifetime. Robyn Seely suggested listing the treatment centers on the PA forms.

e. Board Action:

1. Suggested PA criteria:

- a)** Genetic testing to confirm the presence of Biallelic RPE65 mutations
- b)** Age \geq 12 months
- c)** Presence of viable retinal cells
- d)** Single injection in each eye, at least six days apart
- e)** One injection per eye per lifetime

2. Motion to Approve: Eric Cannon. Second: Katherine Smith. All in favor.

8. Public Meeting Adjourned: Aesha Drozdowski motioned to close the meeting. Neal Catalano seconded the motion. All in favor.

9. The next meeting scheduled for Thursday, July 12, 2018 Sublocade.

Audio recordings of DUR meetings are available online at: <https://medicaid.utah.gov/pharmacy/drug-utilization-review-board?p=DUR%20Board%20Audio%20Recordings/>